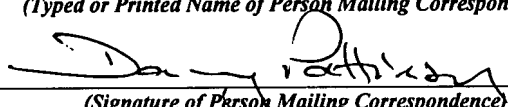


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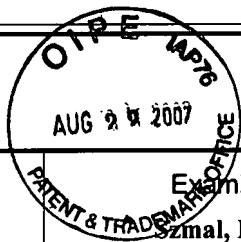
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Applicant(s): Hung			12.024011 DIV	
Application No. 10/762,978	Filing Date 01/22/04	Examiner Szmaj, Brian	Customer No. 0000 38732	Group Art Unit 3736
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Docket No.
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In Re Application Of: Hung



Application No.
10/762,978

Filing Date
01/22/04

Examiner
Szmal, Brian

Customer No.
0000 38732

Group Art Unit
3736

Confirmation No.
5996

Invention: Devices, Methods and Systems for collecting Materials for a Breast Duct

COMMISSIONER FOR PATENTS:

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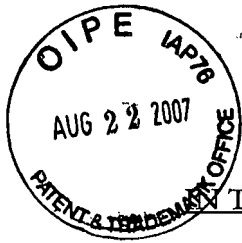
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THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

David HUNG, *et al.*

Serial No. 10/762,978

Filed: January 22, 2004

For: DEVICES, METHODS, AND
SYSTEMS FOR COLLECTING
MATERIALS FOR A BREAST DUCT)

) Examiner: Szmaj, Brian

) Group Art Unit: 3736

) Attorney Docket No.: 12.024011 DIV

August 22, 2007

Commissioner for Patents

P.O. Box 1450

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APPEAL BRIEF

Sir:

This Appeal Brief is filed pursuant to the "Notice of Appeal to the Board of Patent Appeals and Interferences" filed June 26, 2007.

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Real Party in Interest.

The real party in interest in this appeal is Cytyc Corporation, Inc., the assignee of the above-referenced patent application.

Related Appeals and Interferences.

There are no related appeals and/or interferences involving this application or its subject matter.

Status of Claims.

Claims 79-100 were previously pending. Claims 79-89 have been cancelled. Claims 90-100 have been rejected. Claims 90-100 are the subject of this appeal.

Claims 90-100 were rejected on the grounds of non-statutory obviousness-type double patenting as being unpatentable over claims 62-65 and 68 of U.S. Patent No. 6,689,070 B2.

Appellants assert that a terminal disclaimer may be filed at the time the claims are indicated to be allowable and therefore the Appellants have requested that this issue be held in abeyance until such a time that there is allowable subject matter.

Claims 90-100 were rejected under 35 U.S.C. 103(a), as being unpatentable over USP 5,843,023 to Cecchi in view of Hou *et al.* (A Simple Method of Duct Cannulation and Localization for Galactography before Excision in Patients with Nipple Discharge).

The claims appear in Appendix A. No other claims are pending.

Status of Amendments.

All of Appellant's amendments have been entered.

Summary of Claimed Subject Matter.

Pending independent claim 90 of the present invention is directed to a method for lavaging a human breast duct, said method comprising: inserting a distal end of a catheter through a ductal orifice and into a distal lumen of a duct or ductal network; said catheter comprising a proximal end and a distal end, and an internal lumen extending between said proximal and distal ends, said distal end including an opening for delivering lavage fluid within said duct and receiving fluid from within the duct; and a manifold hub in fluid communication with said catheter, said manifold hub comprising a distal end having a first port for infusing fluids into said hub and a second port for collecting fluid from within said hub; infusing a lavage fluid through said first port and into said hub; infusing lavage fluid from said hub into the duct or ductal network through said internal lumen of said catheter; withdrawing the lavage fluid and substances borne by the lavage fluid from the duct or ductal network through the same said lumen of said catheter and into said hub; and delivering said lavage fluid into a collection device through said second port of said hub.

A summary claim 90 may be found at page 2, paragraph [0016] of the specification as well as Figure 7C.

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Grounds of Rejection to be Reviewed on Appeal.

Issue 1--Whether claims 90-100 are patentable under 35 U.S.C. 103(a) over USP 5,843,023 to Cecchi in view of Hou *et al.* (A Simple Method of Duct Cannulation and Localization for Galactography before Excision in Patients with Nipple Discharge).

ARGUMENT

Issue 1-- Whether claims 90-100 are patentable under 35 U.S.C. 103(a) over USP 5,843,023 to Cecchi in view of Hou et al. (A Simple Method of Duct Cannulation and Localization for Galactography before Excision in Patients with Nipple Discharge).

Claims 90-100 were rejected under 35 U.S.C. 103(a), as being unpatentable over USP 5,843,023 to Cecchi in view of Hou *et al.* (A Simple Method of Duct Cannulation and Localization for Galactography before Excision in Patients with Nipple Discharge).

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. Second, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Finally, there must be a reasonable expectation of success. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

I. The prior art references (or references when combined) are not enabled and do not teach or suggest all the claim limitations.

To establish a *prima facie* case of obviousness includes the criteria that all of the limitations of

the claims must be taught or suggested by the prior art. *In re Royka* 490 F.2d 981 (C.C.P.A. 1974).

Since, under the obviousness standard, the prior art must teach or suggest all the limitations of the claims, then it is axiomatic that non-enabling disclosures should not be considered prior art (See *e.g.*, *In re Wilder*, 429 F.2d 447, 166 USPQ 545, 548 (C.C.P.A. 1970).

In the Office Action of October 30, 2006, the Examiner stated that U.S. Pat No. 5,843,023 to Cecchi (hereinafter "Cecchi") discloses:

"...an aspiration needle with a side port and further disclose: a manifold hub (17) in fluid communication with the cannula (13), the manifold hub (17) comprising a distal end having a first port (29) for infusing fluids into the hub (17) and a second port (16) for collecting fluid from within the hub (17); infusing a lavage fluid through the first port (29) and into the hub (17) (See Figures 1 and 2; and Column 5, lines 21-24); infusing lavage fluid from the hub (17) into the target site through the internal lumen (30) of the cannula (13) (See Figures 1 and 2; and Column 5, lines 21-24); withdrawing the lavage fluid and substances borne by the lavage fluid from the target site through the lumen (30) of the cannula (13) and into the hub (17); ..." (see page 5, section 8; second paragraph).

The Appellant respectfully disagrees that Cecchi teaches or suggests a method for lavaging a human breast duct comprising inserting a distal end of a catheter through a ductal orifice and into a distal lumen of a duct or ductal network the catheter comprising a proximal end and a distal end, and an internal lumen extending between the proximal and distal ends, the distal end including an opening for delivering lavage fluid within the duct and receiving fluid from within the duct; and a manifold hub in fluid communication with the catheter, the manifold hub comprising a distal end having a first port for infusing fluids into the hub and a second port for collecting fluid from within the hub.

In particular, the Appellant disagrees with the Examiner's assertion that Cecchi discloses "...an aspiration needle with...a manifold hub (17) in fluid communication with the cannula (13)..."

Element (17) in Cecchi is not a manifold hub. As evidenced in Figures 1 and 2 of Cecchi, element (17) is a "T-connector" where a single lumen 17 Ga. cannula (13) and a Teflon tube (23) intersect.

In the Final Office Action of April 3, 2007, the Examiner disagreed with the Appellant's assertion that element (17) in Cecchi is not a manifold hub, stating "A manifold hub is nothing more than a means of uniting various elements (in the instant case lumens) and connecting them at a single point." (page 6; first full paragraph) The Appellant respectfully disagrees.

A manifold hub generally comprises a space with a plurality of inlets or inlet ports and a single outlet as demonstrated by element (20) in Figures 1-5 in the Appellant's specification. A manifold hub also inherently suggests a space where fluids can be collected or mixed. The device described in Cecchi contains merely one inlet and one outlet and no area or space for the collection of fluid.

As further evidence that Cecchi does not teach or suggest a manifold hub, the method of the present invention describes a manifold hub in fluid communication with a catheter. In Cecchi, element (17) is not in fluid communication with catheter (13). As described in Cecchi, element (17) is a "...polycarbonate plastic, with threaded tube connectors 14, 15, 16 holding the resilient conduit 20, 21 silicone tubing and single lumen cannula 13." (column 4; lines 61-64) (emphasis added). Element (17) of Cecchi has no physical connection with the fluid which passes through the lumen of catheter (13) and thus cannot be in fluid communication with catheter (13).

As even further evidence that Cecchi does not teach or suggest a manifold hub, the method of the present invention describes withdrawing lavage fluid and substances borne by the lavage fluid

from the duct or ductal network through the same said lumen of said catheter and into said hub.

The device of Cecchi does not teach or suggest the withdrawal of fluid through a lumen of catheter (13) and into a hub (17). Fluid merely passes through catheter (13) and into the collection vial (26).

Thus, element (17) in Cecchi is clearly not a manifold hub. Hou *et al.* cannot make up for the deficiency of Cecchi because Hou does not teach or suggest a catheter comprising a manifold hub.

Lastly, neither Cecchi nor Hou et al. teach or suggest a method for the collection of breast duct cells. Cecchi teaches the collection of oocytes and Hou et al. teach a method for injecting dye into a breast duct.

Thus, the Examiner has not established a *prima facie* case of obviousness because Cecchi does not teach or suggest, either alone or in combination with Hou *et al.*, a method for lavaging a human breast duct comprising inserting a distal end of a catheter through a ductal orifice and into a distal lumen of a duct or ductal network the catheter comprising a proximal end and a distal end, and an internal lumen extending between the proximal and distal ends, the distal end including an opening for delivering lavage fluid within the duct and receiving fluid from within the duct; and a manifold hub in fluid communication with the catheter, the manifold hub comprising a distal end having a first port for infusing fluids into the hub and a second port for collecting fluid from within the hub.

II. There is no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings.

To establish a *prima facie* case of obviousness, it is necessary for the Examiner to present

evidence, preferably in the form of some teaching, suggestion, incentive or inference in the applied references, or in the form of generally available knowledge, that one having ordinary skill in the art would have been motivated to make the claimed invention. See, e.g., *Carella v. Starlight Archery*, 804 F.2d 135, 231 USPQ 644 (Fed. Cir. 1986); and *Ashland Oil, Inc. v. Delta Resins and Refractories, Inc.*, 776 F.2d 281, 227 USPQ 657 (Fed. Cir. 1985).

A new combination of elements can be patented “whether it be composed of elements all new, partly new or all old.” *Rosmount, Inc. v. Beckman Instruments, Inc.*, 727 F.2d 1540, 1546, 221 USPQ 1, 7 (CAFC 1984). The Court of Appeals for the Federal Circuit has forcefully stated that a claim rejection must provide a specific motivation in the art for combining elements from cited art in order to establish obviousness of a new combination.

“[C]ase law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. ... Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor’s disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight. ... [Evidence of a suggestion, teaching, or motivation to combine] must be clear and particular. ... Broad conclusory statements regarding the teaching of multiple references, standing alone, are not ‘evidence.’ ... [A] reference-by-reference, limitation-by-limitation analysis fails to demonstrate how the [cited] references teach or suggest their combination ... to yield the claimed invention,” and a conclusion of obviousness based on such an analysis “as a matter of law, cannot stand.” *In re Dembiczak*, 175 F.3d 994, 999, 1000, 50 USPQ2d 1614, 1617, 1618 (Fed. Cir. 1999), emphasis added.

Dembiczak involved patent claims to “a large trash bag made of orange plastic and decorated with lines and facial features, allowing the bag, when filled with trash or leaves, to resemble a Halloween-style pumpkin, or jack-o'-lantern.” *Dembiczak*, 996, 1616. The prior art cited by the Board included: a book describing how to teach children to make a “Crepe Paper Jack-O-Lantern;”

a book describing a method of making a "paper bag pumpkin" by stuffing a bag with newspapers, painting it orange, and then painting on facial features with black paint; a U.S. Patent describing a bag apparatus wherein the bag closure is accomplished by the use of folds or gussets in the bag material; design patents issued to Dembiczak; and prior art "conventional" plastic lawn or trash bags. The Federal Circuit held that the claimed pumpkin-style trash bag was not obvious because there was no clear, particular motivation to combine the cited references.

This holding of *Dembiczak* that evidence of motivation to combine must be clear and particular to establish obviousness has been emphasized over and over again by the Federal Circuit since *Dembiczak* was decided. It was strongly reemphasized in *Ruiz v. A.B. Chance Co.*, 57 USPQ2d 1161 (Fed. Cir. 2000):

In order to prevent a hindsight-based obviousness analysis, we have clearly established that the relevant inquiry for determining the scope and content of the prior art is whether there is a reason, suggestion, or motivation in the prior art or elsewhere that would have led one of ordinary skill in the art to combine the references. See, e.g., In re Rouffet, 149 F.3d 1350, 1359, 47 USPQ2d 1453, 1459 (Fed. Cir. 1998) ("[T]he Board must identify specifically . . . the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious."); In re Dembiczak, 175 F.3d at 999, 50 USPQ2d at 1617 ("Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references."). "Determining whether there is a suggestion or motivation to modify a prior art reference is one aspect of determining the scope and content of the prior art, a fact question subsidiary to the ultimate conclusion of obviousness." Sibia Neurosciences, Inc. v. Cadus Pharma. Corp., 225 F.3d 1349, 1356, 55 USPQ2d 1927, 1931 (Fed. Cir. 2000); Tec Air, Inc. v. Denso Mfg. Inc., 192 F.3d 1353, 1359, 52 USPQ2d 1294, 1298 (Fed. Cir. 1999) (stating that the factual underpinnings of obviousness include whether a reference provides a motivation to combine its teachings with those of another reference).

... there is "a general rule that combination claims can consist of combinations of old elements as well as new elements," Clearstream Wastewater Sys. v. Hydro-Action, Inc., 206 F.3d 1440, 1446, 54 USPQ2d 1185, 1189-90 (Fed. Cir. 2000),

"[t]he notion . . . that combination claims can be declared invalid merely upon finding similar elements in separate prior patents would necessarily destroy virtually all patents and cannot be the law under the statute, § 103." Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1575, 1 USPQ2d 1593, 1603 (Fed. Cir. 1987); Arkie Lures, Inc. v. Gene Larew Tackle, Inc., 119 F.3d 953, 957, 43 USPQ2d 1294, 1297 (Fed. Cir. 1997) ("It is insufficient to establish obviousness that the separate elements of the invention existed in the prior art, absent some teaching or suggestion, in the prior art, to combine the elements."). *Rui* at 1167

Applying this standard to the references cited by the Examiner, it is clear that the Examiner has failed to meet the burden of providing evidence of a motivating force sufficient to impel a person of ordinary skill in the art to combine the teachings in the applied references in the proposed manner to arrive at the claimed invention. The motivation cited in the Office Action for the proposed combination is as follows:

"...it would have been obvious to one of ordinary skill in the art to modify the method of Cecchi to utilize the device for lavaging a breast duct, as per the teachings of Hou et al., since it would provide a means of utilizing a single syringe for creating a vacuum and aspirating a sample and a second syringe for providing a lavage fluid."

(see October 20, 2006 Office Action; page 7, second paragraph).

This statement does not provide the clear, particular suggestion in the art for making the specific claimed combination as is required. The Examiner has failed to meet the burden of providing evidence of a motivating force sufficient to impel a person of ordinary skill in the art to use a method for lavaging a human breast duct, the method comprising inserting a distal end of a catheter through a ductal orifice and into a distal lumen of a duct or ductal network; the catheter comprising a proximal end and a distal end, and an internal lumen extending between said proximal

and distal ends, said distal end including an opening for delivering lavage fluid within the duct and receiving fluid from within the duct; and a manifold hub in fluid communication with the catheter, the manifold hub comprising a distal end having a first port for infusing fluids into the hub and a second port for collecting fluid from within the hub; infusing a lavage fluid through the first port and into the hub infusing lavage fluid from the hub into the duct or ductal network through the internal lumen of the catheter withdrawing the lavage fluid and substances borne by the lavage fluid from the duct or ductal network through the same lumen of the catheter and into the hub; and delivering the lavage fluid into a collection device through the second port of said hub.

Cecchi teaches a device for collecting an oocyte from the ovary of a patient. The device of Cecchi contains a beveled tip in order to puncture a follicle on an ovary (see abstract). The Examiner has failed to provide evidence of a motivating force sufficient to impel a person of ordinary skill in the art to combine the teachings of Cecchi and Hou *et al.* Cecchi does teach or suggest the use of an aspiration needle for collecting ductal lavage fluid. In fact, the beveled end of the needle described in Cecchi would cause damage if used in a fragile breast duct. Since Cecchi does not teach or suggest a device that is sized or designed for use in a breast duct, one of skill in the art would not have been motivated to combine the device of Cecchi with the method of Hou *et al.*

In the Final Office Action of April 3, 2007, the Examiner argued that "...Cecchi clearly teaches the use of a means of lavaging an organ (ovary) to obtain cells (oocytes). Hou *et al.* teaches a system of that is similar to Cecchi, but is used to lavage a breast duct." (page 8; section 6). The Appellant respectfully disagrees.

The system taught by Hou et al. is not similar to that taught by Cecchi. Hou *et al.* teaches a method of injecting contrast material into a breast duct for contrast imaging (galactography). Cecchi teaches a method of collecting oocytes. The Examiner has not provided any evidence that one skilled in the art, even if relying on common sense, would be motivated to modify a device whose primary intended purpose is for the injection of dye into a breast duct with a device whose primary intended purpose is for the collection of oocytes by the use of percutaneous needle aspiration to arrive at the claimed invention. The obviousness rejection is based on hindsight from these disparate references to provide random elements of the claims. There is no clear, particular motivation in the references to reach the claimed invention.

Thus, a *prima facie* case of obviousness has not been established because the Examiner has not presented evidence that one having ordinary skill in the art would have been motivated to combine the device of Cecchi with the method of Hou *et al.* to make the claimed invention. In view of the foregoing, the rejection of claims 90-100 under U.S.C. § 103(a), should be reversed.

CONCLUSION

In view of the arguments presented above, the Appellant contend that each of claims 90-100 is patentable. Therefore, reversal of the rejections under 35 U.S.C. §103(a) is respectfully solicited.

It is not believed that any additional extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 502855 referencing attorney docket number 12.024011.

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APPENDIX A: PENDING CLAIMS

90. A method for lavaging a human breast duct, said method comprising: inserting a distal end of a catheter through a ductal orifice and into a distal lumen of a duct or ductal network; said catheter comprising a proximal end and a distal end, and an internal lumen extending between said proximal and distal ends, said distal end including an opening for delivering lavage fluid within said duct and receiving fluid from within the duct; and a manifold hub in fluid communication with said catheter, said manifold hub comprising a distal end having a first port for infusing fluids into said hub and a second port for collecting fluid from within said hub; infusing a lavage fluid through said first port and into said hub; infusing lavage fluid from said hub into the duct or ductal network through said internal lumen of said catheter; withdrawing the lavage fluid and substances borne by the lavage fluid from the duct or ductal network through the same said lumen of said catheter and into said hub; and delivering said lavage fluid into a collection device through said second port of said hub.

91. The method according to claim 90 wherein the step of infusing the lavage fluid includes the step of applying a positive infusion pressure within the internal lumen.

92. The method according to claim 91 wherein the positive pressure is applied by a syringe.

93. The method according to claim 90 wherein the step of infusing the lavage fluid includes the

step of applying a positive infusion pressure within the hub.

94. The method according to claim 93 wherein the positive pressure is applied by a syringe.

95. The method of claim 90 wherein the step of withdrawing the lavage fluid and substances includes the step of applying negative pressure within the internal lumen.

96. The method according to claim 95 wherein the negative pressure is applied by said collection device.

97. The method according to claim 96 wherein the collection device is a syringe.

98. The method of claim 90 wherein the step of withdrawing the lavage fluid and substances includes the step of applying negative pressure within the hub.

99. The method according to claim 98 wherein the negative pressure is applied by said collection device.

100. The method according to claim 99 wherein the collection device is a syringe.

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APPENDIX B: EVIDENCE

NONE

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APPENDIX C: RELATED PROCEEDINGS

NONE